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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,101	07/08/2003	Ying Luo	RIGL-010CIP3	5361
24353 7590 09/07/2007 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			EXAMINER CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/616,101

**Applicant(s)**

LUO ET AL.

**Examiner**

Iqbal H. Chowdhury, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication; even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-43 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 38-43, and 45-47 are currently pending and are present for examination.

Applicant's cancellation of claim 43 in a communication filed on 6/13/2007 is acknowledged. Claims 45-47 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 38-43 are now under consideration.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/13/2007 has been entered.

Applicants' amendments and arguments filed on 6/13/2007 have been fully considered but are not deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

#### ***New-Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 is indefinite in the recitation of "bioactive agent" as it is unclear what the scope of activities that is encompassed by this term includes. On paragraph [0145] of the specification, applicants define the term "bioactive agent" as "protein, small

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organic molecule, carbohydrates (including polysaccharides), polynucleotide, lipids, etc". As such this is a non-exhaustive list and applicants definition does not set forth what properties must be present in the agent for it to be "bioactive" such that other agents could be identified.

***Maintained-Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Previous rejection of Claims 38-40, and 42 under 35 U.S.C. 102(e) as being anticipated by any or all of the following references; Christenson et al. (US 20030190739A1, effective filing <sup>see IDS</sup> date 6-29-1999), and Daly et al. (US 20020037582A1, with effective filing date 9-23-1998<sup>see IDS</sup>) is maintained and claim 43 is included in this rejection.

Claims 38-40, and 42-43 of the instant application are drawn to a cell lysate composition comprising a recombinant Tankyrase H protein, a source ADP –ribose wherein said enzyme has ADP-ribose polymerase activity, wherein said composition comprises a test agent, a candidate bioactive agent such as a organic molecule of less than 2500 Da and wherein said polypeptide has an amino acid sequence that is at least 95% identical to SEQ ID NO: 3 or 4, wherein the composition is a cell lysate.

Christenson et al. disclose a polypeptide Tankyrase H (99.9% identical to SEQ ID NO: 3 and 4 of the instant application), which similar to PARP, cell lysate, which is a source of ADP–ribose (see paragraph [0105]). Christenson et al. also teach a fusion protein (paragraph [0066]).

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Claims 39 and 40 are included in this rejection because Christenson et al. teach cell lysate, which inherently contains many biologically active peptides within the scope of the claim.

Daly et al. teach a protein, which is 97% identical to SEQ ID NO: 3 and 4, inherently a Tankyrase H protein having PARP activity. Daly et al. also teach a fusion protein of said protein. Claims 39 and 40 is included in this rejection because Daly et al. teach cell lysate, which inherently contains ADP-ribose and many biologically active peptides within the scope of the claim.

Applicants argue that Daly's cell extracts can be made by lysing cells under denaturing conditions (e.g., by boiling the cells or by lysing the cells in a buffer that contains chemical denaturants), Daly's cell extracts do not necessarily contain enzymatically active Tankyrase H protein, as required by the claims. This is not found persuasive because Daly et al. do not disclose that cell lysate was prepared by boiling or with denaturing agent but recites cell lysate (paragraph [0049]). Cell lysate can be prepared by sonication or freeze thawing, which would not make the enzyme inactive. Similarly, Christenson et al. indeed teach using cell lysate, which is prepared by sonication, wherein said cell lysate comprises activity (see [paragraph 0105]).

Thus above references anticipate claims 38-40, and 42-43 of this application as written. Therefore, the rejection is maintained.

### ***Conclusion***

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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